

REMARKS

This is in response to the Examiner's Office Action mailed January 2, 2004 and Applicants' telephone interview with Examiners J. A. Goldberg and J. Feldman, Ph.D. on April 8, 2004. Claims 1-21, 23 and 32-42 have been canceled. Claim 22 has been amended. New Claims 43-46 have been added. Claims 22, 24-31 and 43-46 are now pending.

Applicants express their appreciation to the Examiners for conducting the telephone interview. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

I. Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 32, 33, and 35 under 35 U.S.C. § 112, First Paragraph for lack of enablement. Applicants' cancellation of claims 32-36 renders the rejection moot.

II. Rejections under 35 U.S.C. § 103(a)

1) Rejection of claims 1, 15, 22, and 25

The Examiner rejects claims 1, 15, 22 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Weinberger et al. in view of Mbayed et al.

Applicants cancel claims 1-21 and amend independent claim 22 to specify a method for detecting a HBV variant that may have escaped immunological detection of HBV surface antigen (HBsAg). Support for the claim language "HBV that may have escaped immunological detection of HBsAg" appears in the Specification, for example, on page 31, EXAMPLE 1, lines 6-11. Support for the claim language "determining whether the amplified product comprises nucleic acid encoding major HBV surface antigen (SHBsAg) having a mutation at amino acid positions 130, 131, 133 and 145" appears in the Specification, for example, on page 31, EXAMPLE 1, lines 27-35; and in Table 2 on page 33.

As acknowledged by the Examiner, Weinberger et al. does not specifically teach using primers of SEQ ID NOS: 1 and 2 to detect HBV variants. Neither does Mbayed et al. Further

neither Weinberger et al. nor Mbayed et al. teaches or suggests using the primers of SEQ ID NOs: 1 and 2 to detect HBV strains that may have escaped immunological detection of the HBV surface antigen (HBsAg), i.e., HBV strains tested negative for HBsAg. Moreover, none of the references teaches or suggests detecting the HBV strains through detection of a mutation in amino acid positions 130, 131, 133 and 145 of major HBV surface antigen (SHBsAg).

In view of the failure of the cited references to teach or suggest the claimed invention, Applicants submit that a prima facie case of obviousness has not been established under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is respectfully requested.

2) Rejection of claim 4

The Examiner rejects claims 4 under 35 U.S.C. § 103(a) as being unpatentable over Weinberger et al. in view of Mbayed et al. and further in view of Mason et al.

Applicants cancel claim 4, and add new claim 43 depending from claim 22. As discussed in detail above, independent claim 22 as amended specifies a method for detecting a HBV strain that may have escape immunological detection of HBsAg through detection of a mutation in amino acid positions 130, 131, 133 and 145 of SHBsAg. Neither Weinberger et al. nor Mbayed et al. teaches or suggests the claimed invention. Mason et al. merely teaches reverse transcribing HBV RNA.

Thus, the cited references, each alone or in combination, fail to teach or suggest the claimed method. New claim 43 is therefore not only novel but also non-obvious under 35 U.S.C. § 103(a).

2) Rejection of claims 5, 6, and 13

The Examiner rejects claims 5, 6, and 13 under 35 U.S.C. § 103(a) as being unpatentable over Weinberger et al. in view of Mbayed et al. and further in view of Dattagupta et al. Applicants' cancellation of claims 5, 6, and 13 renders the rejection moot.

3) Rejection of claim 14, 16-21, 24, and 26-31

The Examiner rejects claims 14, 16-21, 24, and 26-31 under 35 U.S.C. § 103(a) as being unpatentable over Weinberger et al. in view of Mbayed et al. and further in view of Thanavala et al. and Suzuki et al.

Applicants cancel claims 14 and 16-21, and amend independent claim 22 to specify a method for detecting a HBV strain that may have escape immunological detection of HBsAg through detection of a mutation in amino acid positions 130, 131, 133 and 145 of SHBsAg. Neither Weinberger et al. nor Mbayed et al. teaches or suggests using the primers of SEQ ID NOs: 1 and 2 to detect HBV strains that may have escaped immunological detection of HBsAg, i.e., HBV strains tested negative for HBsAg. Thanavala et al. and Suzuki et al. merely disclose a mutation in amino acid position 130, 133, or 145. Thanavala et al. and Suzuki et al. fail to supply the claim elements missing in Weinberger et al. and Mbayed et al. that are required for the establishment of a prima facie case of obviousness under 35 U.S.C. § 103(a). Withdrawal of rejection is therefore respectfully requested.

CONCLUSION

Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit Examiner to expedite prosecution of this patent application to issuance. Should Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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